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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,541	04/13/2001	Kengo Akimoto	001560-396	7683
7590 04/01/2004				
Ronald L Grudziecki Burns Doane Swecker & Mathis PO Box 1404 Alexandria, VA 22313-1404		EXAMINER SRIVASTAVA, KAILASH C		
		ART UNIT 1651		PAPER NUMBER

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/807,541	<b>Applicant(s)</b> AKIMOTO ET AL.	
	<b>Examiner</b> Dr. Kailash C. Srivastava	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34, 36-43, 45-49, 51, 52, 54-68, 70-77, 79 and 80 is/are pending in the application.
- 4a) Of the above claim(s) 15-29, 45-49, 51, 59-64, 74-77, 79 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 30-34, 36-43, 52, 54-58, 65-68 AND 70-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Applicants' amendment and response filed 01/15/2004 in response to Office Action mailed 07/15/2003 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. Claims 8-9, 11, 38-39, 47-49, 52, 57, 70 and 76-77 have been amended
3. Claims 35, 44, 50, 53, 69 and 78 have been cancelled.
4. In view of Applicants' election made in applicants' response filed June 21, 2002, Claims 15-29, 45-51, 59-64 and 74-80 have previously been withdrawn from further consideration (See Office Actions mailed September 10, 2002; July 15, 2003 as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. In view of applicants' previous response cited *supra* and applicants' response filed 01/15/2004, Examiner suggests that to expedite prosecution, non-elected claims 15-29, 45-49, 51, 60-64, 74-77 and 79-80 be canceled in response to this Office action.
5. Claims 1-14, 30-34, 36-43, 52, 54-58, 65-68 and 70-73 are examined on merits.

### ***Claim Rejections - 35 U.S.C. § 112***

6. Claims 1-14, 30-34, 36-43, 52, 54-58, 65-68 and 70-73 stand rejected under 35 U.S.C. § 112, first paragraph for the reasons of record on pages 3-5 items 9 and 10 of the Office Action cited *supra*.

In response to the rejections under 35 U.S.C. § 112, first paragraph in the Office Action cited *supra*, applicants argue that undue experimentation will not be required for one skilled in the art to practice the invention as claimed" because "One skilled in the art could readily practice the invention" based on the details provided in the specification on obtaining the mutants, and publicly availability of microorganisms in addition to SAM 2241 and SAM 2242.

Applicants' arguments in response filed 01/15/2004 regarding the rejections under 35 U.S.C. § 112, first paragraph in the Office Action mailed 07/15/2003 cited *supra* have been fully considered but are not deemed persuasive for the reasons of record on pages 3-5 items 9 and 10 of the Office Action cited *supra*. Moreover, applicants' invention has clearly been exemplified with only two strains, i. e., 2241 and 2242 of *Mortierella alpina* in the specification as presently written and is not enabled for any and all microorganisms which extracellularly secrete encapsulated lipid vesicles as claimed (including any and all of the microorganisms recited on pages 9-10 of the instant specification).

### **CONCLUSION**

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

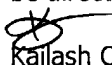
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No Claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(571) 272-0923

March 29, 2004



CHRISTOPHER R. TATE  
PRIMARY EXAMINER